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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/823,139 | 04/13/2004 | John C. Oslund | ev31010USD1 | 4537 |
| 9561 | 7590 | 01/20/2006 | EXAMINER | |
| POPOVICH, WILES & O'CONNELL, PA 650 THIRD AVENUE SOUTH SUITE 600 MINNEAPOLIS, MN 55402 | | | EREZO, DARWIN P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |

DATE MAILED: 01/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/823,139

Applicant(s)

OSLUND ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18,30,31,56-59 and 61-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18,30,31,56-59 and 61-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-13, 16-18, 30, 31, 56-59 and 61-70 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,814,064 to Daniel et al.

Fig. 16a-16b of Daniel teaches a distal protection device comprising a filter basket **198** having closed distal end and an open proximal end; a self expanding radial member **200** (col. 9, lines 29-31) associated with the filter basket in proximity to the proximal end thereof, said member being adapted to maintain the proximal end of the filter basket in an open configuration (Fig. 16B); wherein an opposite end of the filter basket is mounted on a guidewire **196** (the distal portion of the filter is loosely mounted on said guidewire); wherein the filter basket is in a shape of a windsock, wherein the filter basket includes a tube through which the guidewire extends (the filter basket is configured as a tube in which the guidewire extends therethrough); wherein said radial member **200** comprises a loop (a circular loop); wherein the radial member is formed as a "C", "J" or spiral configuration (Daniel teaches other embodiments that shows an expandable member having said configurations, such as Fig. 1); wherein the expandable member is formed from nitinol (col. 9, line 53); wherein the loop in its expanded state defines a lane that is substantially perpendicular (90 degrees) to the

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guidewire (Fig. 16a); wherein the filter basket and loop are adapted to be collapsed to fit into a small diameter delivery catheter (when the sheath **204** is at it's proximal position); wherein the end of the filter basket that is free floating cooperates with the guidewire in a manner which allow the free floating end to move rotationally and axially along the guidewire (since the free end is not attached and is separated from the guidewire by the radius of the radial member **200**); wherein the device comprises alignment maintenance means for precluding rotation of the loop relative to the proximal end of the filter basket (since Daniel teaches other embodiments with the member directly attached to the guidewire at the proximal end); wherein the maintenance means can comprise a plurality of tethers (another embodiment shown in Fig. 6, tethers **46**).

Daniel also teaches a method of capturing debris formed during a medical procedure in human vasculature, comprising the steps of inserting a catheter **120** containing a distal protection device in collapsed configuration into human vasculature (see rejection above); deploying the distal protection device on a distal side of the vasculature affected by a medical procedure; maintaining the distal protection device generally concentrically within the vasculature; and capturing debris produced by the medical procedure within the distal protection device (Fig. 12)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. ('064) as recited above, and in view of US 6,001,118 to Daniel et al. ('118).

The '064 reference teaches all the limitations of the claims except for the device having radiopaque material. However, the '118 reference teaches a distal protection device that comprises radiopaque material (col. 14, lines 60-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add radiopaque material to the '064 reference because it allows a practitioner to monitor the position of the device within the vessel using a scope.

Response to Arguments

5. Applicant's arguments, see paragraph 4 of the Remarks, filed 10/27/05, with respect to the expandable member have been fully considered and are persuasive. However, upon further consideration of the reference, it has been discovered that Daniels teaches another embodiment that uses a self-expandable radial member.

Terminal Disclaimer

6. The terminal disclaimer filed on 10/27/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6740061 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PRIMARY EXAMINER